EXHIBIT A

Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Arlington, Virginia

Appeal of: [redacted]	OMHA Appeal No.: **1-8429016928**
	QIC Appeal No.: **1-8292970718**
Enrollee:	Medicare: **Part B-DME**
Medicare No.:	Before: **Leslie Holt** **Administrative Law Judge**

DECISION

Medicare Part B does not cover the Appellant's Tumor Treatment Fields Therapy (TTFT), or electrical stimulation device used for cancer treatment (E0766), as the record failed to establish medical reasonableness and necessity set forth in the LCD L34823, CMS Manuals, and Title XVIII §§ 1862(a)(1)(A) of the Social Security Act. Accordingly, an **UNFAVORABLE** decision is entered for [redacted] (the "Appellant"/"Beneficiary"). The Supplier's liability for the cost of the non-covered items may not be limited pursuant to Title XVIII § 1879 of the Social Security Act.

PROCEDURAL HISTORY

The Appellant/Beneficiary submitted claims to the Medicare Administrative Contractor ("Contractor") seeking payment for the Tumor Treatment Field Therapy (TTFT) (E0766) for treatment of Grade II glioma/oligoastrocytoma furnished to the Beneficiary on June 11, 2018, July 11, 2018, and August 11, 2018 ("Dates of Service"). The Contractor denied coverage initially, and upheld this decision on redetermination, findings that tumor treatment field therapy was not covered by Medicare because the currently published studies and medical literature did not clearly document the effectiveness of the device. (Exh. 1, pp. 1-6; Exh. 2, pp. 30-33).

The Appellant requested that a Qualified Independent Contractor ("QIC") reconsider the Contractor's denial. (Exh. 2, pp. 19-20). On March 19, 2019, the QIC issued an unfavorable reconsideration decision, concluding that the peer-reviewed and evidence based literature regarding clinical trials of TTFT were limited in number and not non-biased, as the clinical trials were not independent and were funded by Novocure. Furthermore, it noted that the DME MACs have not issued a new LCD differentiating or providing coverage for newly diagnosed glioblastoma. It found the Supplier, Novocure, Inc., liable for the denied charges, as the Beneficiary was not given advance notice that Medicare would likely deny payment. (Exh. 2, pp. 1-12).

On April 3, 2019, the Office of Medicare Hearings and Appeals ("OMHA") received the Appellant's request for a hearing before an Administrative Law Judge ("ALJ"). (Exh. 3). As the Appellant's request

was timely filed and the amount in controversy meets the jurisdictional requirements, this appeal is properly before OMHA. 42 C.F.R. §§ 405.1002, 405.1006.

A telephonic hearing was held on June 3, 2019. The Appellant/Beneficiary was represented by counsel, Debra Parrish, Esq. and witness Julia Miles, R.N., of Novocure, Inc., the Supplier, who also participated in the hearing. All were sworn and both provided argument and testimony. Prior to the hearing, the Appellant's representative submitted a prehearing brief for the record. (Exh. 4, pp. 13-20). The MAC, Noridian, provided a position paper on the appeal. (Exh. 4, pp. 21-24). These materials are not new evidence and therefore no separate analysis of admissibility is necessary. All exhibits were admitted into evidence without objection. (Hearing CD).

ISSUES

Whether Medicare Part B covers Tumor Treatment Fields Therapy (TTFT), or electrical stimulation device used for cancer treatment (E0766), furnished to the Beneficiary/Appellant on the Dates of Service, and if not, whether Title XVIII § 1879 of the Act limits the liability of the Beneficiary or Supplier with respect to any non-covered services.

FINDINGS OF FACT

1. The casefile contained the Supplier's "Assessment of Need" form, dated December 4, 2015. Notes indicated the Beneficiary was not able to speak in full sentences and that he had short term memory issues. It took him awhile to get words out and he used a walker most of the time, supplementing with a wheelchair for long distances. (Exh. 1, p. 26).

2. The casefile contained an Optune Service Agreement signed by the Beneficiary on December 11, 2015, indicating that the Beneficiary agreed to various supply terms and warranties, and to participate in treatment education sessions conducted by Supplier personnel. It included the signed patient information and consent form and the delivery confirmation indicating that the items were received by the Beneficiary on December 11, 2015. (Exh. 1, pp. 27-41).

3. On April 5, 2017, a neurology progress note indicated that in 2013 the Beneficiary was found to have grade II oligoastrocytoma. He completed 10 cycles of Temodar and had a difficult treatment course including multiple breakthrough seizures and impairments of consciousness of unclear etiology. He started on Optune on December 11, 2015. During the April 5th visit, he denied any headaches, nausea, vomiting, or seizures. His word finding issues were unchanged but stable. His MRI from the visit showed stable enhancement of left posteriors corpus callosum, stable enhancement in periventricular lesions, stable enhancements in the left insular cortex, stable flair in the left frontal lobe, and new lesions. The note indicated that the brain MRI was stable, that the Beneficiary was clinically stable, and that he had improved markedly since the initiation of Optune therapy, which he was tolerating well. The plan to treat the multifocal astrocytoma was intermittent brain MRIs and to continue Optune. Other drug regimens would be considered if there was further progression. (Exh. 2, pp. 25-28; Exh. 1, pp. 43-46).

4. The casefile contained an Optune prescription form signed by the physician on April 13, 2018, for six months of Optune (formerly the NovoTTF-100A System). It as a renewal order. The Beneficiary's diagnosis was multifocal astrocytoma. (Exh. 1, p. 21).

5. Monthly invoices dated June 11, July 11, and August 11, 2018 indicated that the Beneficiary was billed $21,000 per month by the Supplier for the NovoTTF-100A System plus transducers. (Exh. 1, pp. 10-12).

6. The casefile contained a manual regarding instructions for use of Optune (NovoTFF-100A System). (Exh. 1, pp. 72-96).

7. The casefile contained a number of background materials regarding the use of NovoTFF-100A System for treatment of glioblastoma (clinical trials, approvals, and medical articles, etc.)[1]:

- A copy of the NCCN Guidelines in Oncology (Exh. 1, pp. 47-49)
- A *Journal of the American Medical Association* article entitled "Effect of Tumor-Treating Fields Plus Maintenance Temozolomide vs Maintenance Temozolomide Alone on Survival in Patients With Glioblastoma" (Exh. 1, pp. 50-60)
- A *Journal of the American Medical Association* article entitled "Maintenance Therapy With Tumor-Treating Fields Plus Temozolomide vs Temozolomide Alone for Glioblastoma" dated December 15, 2015 (Exh. 1, pp. 61-71)
- The Supplier-produced NovoTFF-100A System Product Dossier for pre-market approval by the FDA for treatment for recurrent glioblastoma multiforme (Exh. 1, pp. 104-153)
- The April 8, 2011 letter from the FDA approving the pre-market application for approval for the NovoTTF-100A System for treatment of adult patients with histologically-confirmed glioblastoma multiforme following histologically or radiologically confirmed recurrence in the supratentorial region of the brain after receiving chemotherapy. (Exh. 1, pp. 99-103)
- Other medical journal articles discussing trials or studies regarding NovoTTF-100A for treatment of glioblastomas (Exh. 1, pp. 97, 154-217; Exh. 2, p. 35)
- A July 26, 2013 letter from CMS responding to an inquiry requesting an informal benefit category determination for the NovoTFF-100A System; CMS concluded that the NovoTTF-100A System fell within the DME benefit category (Exh. 1, p. 98)
- A November 27, 2013 letter from CMS regarding a request to establish two new Level II HCPCS codes to identify Tumor Treating Fields Electronic Field Generator and System Components; CMS modified the codeset following workgroup deliberation and established a national code set: E0766, Electrical Stimulation Device Used For Cancer Treatment, Includes All Accessories, Any Type and A4555, Electrode/tranducer for use with electrical stimulation device used for cancer treatment, replacement only (Exh. 2, pp. 36-41)
- Medicare Contractor decision finding that TTFT or electrical field therapy (E0766) was covered under Medicare or Medicare Advantage (Exh. 1, pp. 218-220)

8. The casefile contained a July 11, 2016 letter written by the Beneficiary appealing Medicare's denial of his physician's prior authorization request for coverage of TTF therapy using the Optune system. He noted that the FDA had approved the treatment for his cancer and noted that his brain tumor was no longer responding to chemotherapy and radiation. He began using Optune on December 11, 2015.

[1] The Appellant's representative provided a CD with additional attachments along with its prehearing brief. The CD included published scientific and medical articles from 2018 and 2018, as well as textbook chapters and a bibliography of TTFT articles. The Appellant's also provided the DME MAC proposed LCD. The CD attached to the casefile and noted in Exh. 4).

Optune was the best option to treat the fatal disease as there were limited treatment options. He has had no side effects from Optune and believes it is helping, as his tumor is slow growing now. (Exh. 1, pp. 13-14).

9. An August 29, 2016 Medicare Appeal Request written and signed by [redacted] requested Medicare coverage and payment of Optune for the Beneficiary. The letter stated that the National Comprehensive Cancer Network ("NCCN") Guidelines were updated in 2015 to include TTFields treatment for recurrent glioblastomas, and demonstrated the favorable outcomes of TTFields therapy using Optune in treating patients such as the Beneficiary. He reviewed the Beneficiary's clinical history and reiterated the difficulty in treating glioblastoma. The letter discussed the process/approach of Optune therapy and recent clinical trial findings/outcomes, and noted other insurance plans or payers that had approved coverage for use of TTFT for the Beneficiary's diagnosis. It noted that the Federal Drug Administration approved the Optune device under the pre-market approval process in April 2011. (Exh. 1, pp. 15-20).

10. An August 26, 2016 letter of medical necessity, signed by [redacted] requested authorization of benefits coverage for Optune for the Beneficiary. The letter stated that the NCCN Guidelines were updated in 2015 to include TTFields treatment for recurrent glioblastomas, and demonstrated the favorable outcomes of TTFields therapy using Optune in treating patients such as the Beneficiary. It noted that the FDA approved the Optune device under the pre-market approval process in April 2011. (Exh. 1, pp. 23-25).

11. The Appellant's representative's letter requesting an ALJ hearing noted that the device and TTFT treatment was approved by the FDA as safe and effective for treatment of glioblastomas. She noted that the Beneficiary's Grade II glioma has progressed and that the progression of lower-grade gliomas are typically considered instances of glioblastoma. Grade II gliomas have a close clinical connection to glioblastomas, a Grade IV glioma. She stated that TTFT is covered by large national payers and that Medicare has paid for numerous claims for medically indistinguishable beneficiaries. She argued that the QIC's determination regarding the lack of peer-reviewed articles and inadequate scope and breath was incorrect, as multiple peer-reviewed articles showed the effectiveness of TTFT. She further argued that the LCD record showed that DMACs had failed to update the LCD to reflect consideration of developments that had occurred in the past five years. She noted that on March, 6, 2019, the Carrier Advisory Committee recommended Medicare coverage of TTFT, finding that peer-reviewed literature showed the treatment to be safe and effective. (Exh. 3, pp. 1-3).

LEGAL FRAMEWORK

I. Administrative Law Judge Authority — *Jurisdiction, Scope of Review and Standard of Review*

Medicare appeals involve a four-level process. First, individuals or organizations seeking payment under the Medicare Program submit claims to Medicare Administrative Contractors ("Contractors") who make initial determinations, and if appealed, redeterminations. 42 C.F.R. § 405.904. The individual or organization may further appeal to a second reviewing entity known as Qualified Independent Contractor ("QICs"). QICs issue reconsideration decisions. *Id.* Thereafter, third level appeals are made to the Office of Medicare Hearings and Appeals ("OMHA") for a hearing before an Administrative Law Judge ("ALJ"). A hearing will be held provided there is a sufficient amount in controversy and the request for hearing is timely filed. Title XVIII § 1869(b)(1)(A) of the Social Security Act. OMHA is

staffed with ALJs who are qualified and appointed pursuant to the Administrative Procedure Act, 5 U.S.C. §§ 500–596 (2012), and conduct *de novo* hearings of fact and law. Title XVIII § 1869 of the Act; *see* 42 C.F.R. § 405.1000(d); 74 Fed. Reg. 65,296, 65,316 (Dec. 9, 2009). To be considered timely filed and therefore entitled to a hearing before an ALJ, a request must generally be filed within 65 days of the QIC's reconsideration decision, and the amount in controversy must meet the annual threshold established by the Secretary of the Department of Health and Human Services. 42 C.F.R. §§ 405.1002, 1006.

The ALJ will consider all issues decided in the initial determination, redetermination, or reconsideration decisions that were not decided entirely in Appellant's favor. 42 C.F.R. § 405.1032(a). However, if the evidence presented before or during the hearing causes the ALJ to question a favorable portion of the prior determination or decision, he or she will notify the Appellant and will consider it an issue at the hearing. *Id.* The ALJ may decide a case on-the-record and not conduct an oral hearing if the evidence in the hearing record supports a finding in favor of appellants on every issue or the appellant waives their right to a hearing. 42 C.F.R. § 405.1038(a)–(b).

II. Principles of Law — *Part B Durable Medical Equipment Benefit, Statutes and Regulations*

The Social Security Act Amendments of 1965 (Pub. Law 89-97, 79 Stat. 286) created the Medicare Program, a federal health insurance program for the elderly (65 years of age and older), disabled, and individuals with specific illnesses, found in Title XVIII of the Social Security Act (the "Act"). 42 U.S.C. § 1395 *et seq.*; Title XVIII § 1811 of the Act. Medicare was originally comprised of two parts: Medicare Part A, the Hospital Insurance program, found at Title XVIII §§ 1811 to 1821 of the Act, and Medicare Part B, the Supplementary Medical Insurance program, found at Title XVIII §§ 1831 to 1848 of the Act.

Part B provides enrolled beneficiaries insurance coverage for a variety of "medical and other health services" and supplies furnished by physicians or by others in connection with physicians' services, outpatient hospital services, and a number of other specific health-related items and services as set forth in Title XVIII § 1832 of the Act. Individuals participate voluntarily in the Medicare Part B program and pay a monthly premium. Title XVIII §§ 1839–1840 of the Act.

Coverage under Part B entitles a beneficiary to have payments made on his or her behalf for reasonable and necessary items of durable medical equipment ("DME"). Title XVIII § 1832 (a)(2)(G) (covering "covered items" which are defined in Title XVIII § 1834(a)(13) to mean durable medical equipment); Title XVIII § 1832(a)(1)(covering "medical and other health services," which in Title XVIII § 1861(s)(6) includes durable medical equipment). Title XVIII § 1861(n) of the Act defines DME to include a variety of equipment and supplies including, but not limited to, oxygen tents, hospital beds, wheelchairs, and blood glucose monitors and test strips.

As a condition for payment, Section 6407 of the Patient Protection and Affordable Care Act of 2010, (Pub. Law 111–148, 124 Stat. 119) created Title XVIII § 1834(a)(11)(b) of the Act, which requires documentation that a physician, PA, NP or CNS has had a face-to-face encounter examination with a beneficiary in the six (6) months prior to the written order for certain items of DME. The specific list of items of DME affected by this requirement was listed in 77 Fed. Reg. 44798 (July 30, 2012). The face-to-face requirement is effective for dates of service beginning in October 2013. Note this section does not apply to Power Mobility Devices ("PMDs") as these items are covered under a separate requirement. CMS, Medicare Learning Network (MLN) Matters: MM8304 (Eff. July 1, 2013).

Medicare covers only those items and services that are reasonable and necessary for treatment of the beneficiary's illness or injury and are supported by sufficient medical documentation to establish compliance with Medicare guidelines. Title XVIII §§ 1862(a)(1)(A), XVIII § 1833(e) of the Act.

Section 1833(e) of the Act states that "[n]o payment shall be made to any provider of services or other person under this part unless there has been furnished such information as may be necessary in order to determine the amounts due such provider or other person under this part for the period with respect to which the amounts are being paid or for any prior period."

The Medicare program found in Title XVIII of the Act is administered through the Centers for Medicare and Medicaid Services ("CMS"), a component of the United States Department of Health and Human Services ("HHS"). CMS promulgates regulations found at Title 42 of the Code of Federal Regulations for administration of the Medicare program. Medicare Part B pays for the rental or purchase of durable medical equipment, if the equipment is used in the patient's home or in an institution that is used as a home. 42 C.F.R. §§ 410.38(a), 410.10(h). DME is defined as equipment furnished by a supplier or home health agency that (1) can withstand repeated use, (2) has an expected life of at least 3 years, (3) is primarily and customarily used to serve a medical purpose, (4) generally is not useful to an individual in the absence of an illness or injury, and (5) is appropriate for use in the home. 42 C.F.R. § 414.202.

III. Principles of Law — *Part B Durable Medical Equipment Benefit, National and Local Policy Guidance*

A National Coverage Determination ("NCD") is a determination by the Secretary of whether a particular item or service is covered by Medicare on a national basis. 42 C.F.R. § 405.1060. The NCDs are made under Title XVIII § 1862(a)(1) of the Act as well as under other applicable provisions. 42 C.F.R. § 405.1060(a)(3). Notably, an NCD is binding on fiscal intermediaries, carriers, QIOs, QICs, ALJs, and the MAC. 42 C.F.R. § 405.1060(a)(4). With respect to ALJ review, an ALJ may not disregard, set aside, or otherwise review an NCD. 42 C.F.R. § 405.1060(b)(1). However, an ALJ may review the facts of a particular case to determine whether an NCD applies to a specific claim for benefits and, if so, whether the NCD was applied correctly to the claim.

In this case, there is no NCD that specifically discusses Tumor Treatment Fields Therapy (TTFT) or an electrical stimulation device used for cancer treatment (E0766). However, NCD 280.1 provides guidance to facilitate the A/B MAC and DME MACs processing of claims. Specifically, when an A/B MAC or DME MAC receives a claim for an item of equipment which does not appear to fall logically into any of the generic categories listed at Section 280.1, the A/B MAC or DME MAC has the authority and responsibility for deciding whether those items are covered under the DME benefit. CMS, Medicare National Coverage Determinations Manual, *(Internet-Only Manual Publ'n 100-3)* ch. 1, § 280.1.

CMS promulgates Medicare Manuals, which represent CMS' program issuances, day-to-day operating instructions, policies, and procedures that are based on statutes, regulations, guidelines, models, and directives. The CMS program components, providers, contractors, Medicare Advantage organizations and state survey agencies use the manuals to administer CMS programs. Under 42 C.F.R. § 405.1062, ALJs are not bound by the manuals, but must give them substantial deference if they apply to a particular case.

Medicare coverage principles for DME are outlined in the Medicare Benefit Policy Manual ("MBPM"), *(Internet-Only Manual Publ'n 100-2)* ch. 15, § 110.

Section 522 of the Benefits Improvement and Protection Act ("BIPA") of 2000, (Pub. Law 106–554, 114 Stat. 2763) created the term "local coverage determination" ("LCD"). An LCD is a decision by a Contractor whether to cover a particular item or service in their jurisdiction based on its reasonableness and medical necessity. These are administrative and educational tools to assist providers in submitting correct claims for payment.

In this case, the Jurisdiction C DME MAC describes its criteria for coverage of Tumor Treatment Fields Therapy (TTFT), including HCPCS code E0766 (electrical stimulation device used for cancer treatment, includes all accessories, any type), in LCD L34823 Tumor Treatment Field Therapy and Policy Article A52711 Tumor Treatment Field Therapy. The relevant sections are included below.

LCD Tumor Treatment Field Therapy (TTFT) (L34823) (Revision effective date: for services performed on or after January 1, 2017)

Coverage Indications, Limitations, and/or Medical Necessity

For any item to be covered by Medicare, it must 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements.

The purpose of a Local Coverage Determination (LCD) is to provide information regarding "reasonable and necessary" criteria based on Social Security Act § 1862(a)(1)(A) provisions.

In addition to the "reasonable and necessary" criteria contained in this LCD there are other payment rules, which are discussed in the following documents that must also be met prior to Medicare reimbursement:

- The LCD-related Standard Documentation Requirements Article, located at the bottom of this policy under the Related Local Coverage Documents section.
- The LCD-related Policy Article, located at the bottom of this policy under the Related Local Coverage Documents section.
- Refer to the Supplier Manual for additional information on documentation requirements.
- Refer to the DME MAC web sites for additional bulletin articles and other publications related to this LCD.

For the items addressed in this LCD, the "reasonable and necessary" criteria, based on Social Security Act § 1862(a)(1)(A) provisions, are defined by the following coverage indications, limitations and/or medical necessity.

Tumor treatment field therapy (E0766) will be denied as not reasonable and necessary.

GENERAL

A Detailed Written Order (DWO) (if applicable) must be received by the supplier before a claim is submitted. If the supplier bills for an item addressed in this policy without first receiving a completed DWO, the claim shall be denied as not reasonable and necessary.

An item/service is correctly coded when it meets all the coding guidelines listed in CMS HCPCS guidelines, LCDs, LCD-related Policy Articles, or DME MAC articles. Claims that do not meet coding guidelines shall be denied as not reasonable and necessary/incorrectly coded.

Proof of delivery (POD) is a Supplier Standard and DMEPOS suppliers are required to maintain POD documentation in their files. Proof of delivery documentation must be made available to the Medicare contractor upon request. All services that do not have appropriate proof of delivery from the supplier shall be denied as not reasonable and necessary.

DOCUMENTATION REQUIREMENTS

Section 1833(e) of the Social Security Act precludes payment to any provider of services unless "there has been furnished such information as may be necessary in order to determine the amounts due such provider." It is expected that the beneficiary's medical records will reflect the need for the care provided. The beneficiary's medical records include the physician's office records, hospital records, nursing home records, home health agency records, records from other healthcare professionals and test reports. This documentation must be available upon request.

GENERAL DOCUMENTATION REQUIREMENTS

In order to justify payment for DMEPOS items, suppliers must meet the following requirements:

- Prescription (orders)
- Medical Record Information (including continued need/use if applicable)
- Correct Coding
- Proof of Delivery

Refer to the LCD-related Standard Documentation Requirements article, located at the bottom of this policy under the Related Local Coverage Documents section for additional information regarding these requirements.

Refer to the Supplier Manual for additional information on documentation requirements.

Refer to the DME MAC web sites for additional bulletin articles and other publications related to this LCD.

POLICY SPECIFIC DOCUMENTATION REQUIREMENTS

Items covered in this LCD have additional policy-specific requirements that must be met prior to Medicare reimbursement.

Refer to the LCD-related Policy article, located at the bottom of this policy under the Related Local Coverage Documents section for additional information

Tumor Treatment Field Therapy (TTFT) Policy Article (A52711) (Revision effective date 1/1/2017)

NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES:

For any item to be covered by Medicare, it must 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements.

Information provided in this policy article relates to determinations other than those based on Social Security Act §1862(a)(1)(A) provisions (i.e. "reasonable and necessary"). Tumor treatment field therapy devices are covered under the Durable Medical Equipment benefit (Social Security Act §1861(s)(6)). In order for a beneficiary's equipment to be eligible for reimbursement the reasonable and necessary (R&N) requirements set out in the related Local Coverage Determination must be met. In addition, there are specific statutory payment policy requirements, discussed below, that also must be met.

Code E0766 is in the frequent and substantial service payment category. Items included in this payment category are reimbursed a single monthly fee schedule amount for the device and all related supplies and accessories. Separate billing of supplies and/or accessories will be denied as unbundling.

Code A4555 is not valid for billing to Medicare. If code A4555 is billed, it will be denied as an invalid code.

POLICY SPECIFIC DOCUMENTATION REQUIREMENTS

In addition to policy specific documentation requirements, there are general documentation requirements that are applicable to all DMEPOS policies. These general requirements are located in the DOCUMENTATION REQUIREMENTS section of the LCD.

Refer to the LCD-related Standard Documentation Requirements article, located at the bottom of this Policy Article under the Related Local Coverage Documents section for additional information regarding GENERAL DOCUMENTATION REQUIREMENTS and the POLICY SPECIFIC DOCUMENTATION REQUIREMENTS.

CODING GUIDELINES

Code E0766 describes devices that generate electromagnetic fields utilized in the treatment of cancer. The electromagnetic energy generated is transmitted to the body by means of surface electrodes or transducers.

This code is inclusive of all associated supplies necessary for the effective use of code E0766 including, but not limited to, transducers/surface electrodes, lead wires, adhesive patches, connectors, conductive gel and skin preps.

Suppliers should contact the Pricing, Data Analysis and Coding (PDAC) Contractor for guidance on the correct coding of these items.

IV. Principles of Law, *Liability*

Under Title XVIII § 1879 of the Act, Beneficiary and/or Provider liability for non-covered Medicare services may be limited under particular circumstances. In pertinent part, limitation of liability may apply to items or services that are excluded under Title XVIII §§ 1862(a)(1)(A) and 1862(a)(9) of the Act, or by reason of a coverage denial described in subsection 1879(g).

Pursuant to Title XVIII § 1879(a)(2) of the Act, Medicare will limit the Beneficiary's liability for non-covered services if he or she did not know, and could not reasonably have been expected to know, that said services were non-covered. Title XVIII § 1879(a)(2) of the Act also limits the Provider or Supplier's liability for non-covered services if it did not know, and could not reasonably have been expected to know, that said services were non-covered. When both the Beneficiary and the Provider's liability may be limited under Title XVIII § 1879 of the Act, Medicare payment will be made as though Title XVIII §§ 1862(a)(1)(A), 1862(a)(9) or 1879(g) of the Act did not apply. Federal regulation sets forth the criteria for determining who knew that services were excluded from coverage as not reasonable and necessary. 42 C.F.R. §§ 411.404 and 411.406.

ANALYSIS

At issue is Medicare Part B coverage for the Appellant's Tumor Treatment Fields Therapy, or the electrical stimulation device used for cancer treatment (E0766). The QIC denied coverage, concluding that the peer-reviewed and evidence based literature regarding clinical trials of TTFT were limited in number and not non-biased, as the clinical trials were not independent and were funded by Novocure. Furthermore, it noted that the DME MACs have not issued a new LCD differentiating or providing coverage for newly diagnosed glioblastoma. It found the Supplier, Novocure, Inc., liable for the denied charges, as the Beneficiary was not given advance notice that Medicare would likely deny payment. (Exh. 2, pp. 1-12).

The Appellant's representative argued that there was no basis to deny Medicare coverage of the TTFT device that has shown to be safe and effective treatment for treatment of glioblastomas, specifically noting that peer-reviewed literature supported the safety and efficacy of the device and TTFT for treatment of the Beneficiary's condition. She contended that that the progression of lower-grade gliomas are typically considered instances of glioblastoma. She stated that TTFT is covered by large national payers and that Medicare has paid for numerous claims for medically indistinguishable beneficiaries. She argued that the QIC's determination regarding the lack of peer-reviewed articles and inadequate scope and breath was incorrect, as multiple peer-reviewed articles showed the effectiveness of TTFT. She further argued that the LCD record showed that DMACs had failed to update the LCD to reflect consideration of developments that had occurred in the past five years. She noted that on March, 6, 2019, the Carrier Advisory Committee recommended Medicare coverage of TTFT, finding that peer-reviewed literature showed the treatment to be safe and effective. (Exh. 3, pp. 1-3; Hearing CD). It is well established that "a claimant . . . has the burden of proving entitlement to Medicare benefits." *Friedman v. Sec'y of Dept. of Health and Hum. Servs.*, 819 F.2d 42, 45 (2d Cir. 1987). Accordingly, it is the Appellant's burden to establish that the TTFT or electrical stimulation device used for cancer treatment (E0766) was reasonable and necessary for treatment of the Beneficiary's condition and otherwise met Medicare coverage criteria.

Despite the above-mentioned argument supporting the efficacy of the TTFT device, Medicare guidelines are clear that TTFT is not covered. The applicable LCD L34823 states, in relevant part, "[t]umor treatment field therapy (E0766) will be denied as not reasonable and necessary." The related Policy Article A52711, states that:

> "[i]nformation provided in this policy article relates to determinations other than those based on Social Security Act §1862(a)(1)(A) provisions (i.e. "reasonable and necessary"). Tumor treatment field therapy devices are covered under the Durable Medical Equipment benefit (Social Security Act §1861(s)(6)). In order for a beneficiary's equipment to be eligible for reimbursement the reasonable and necessary (R&N) requirements set out in the related Local Coverage Determination must be met. In addition, there are specific statutory payment policy requirements, discussed [in the policy article], that also must be met."

The HCPCS code for the TTFT device at issue is E0766. Because TTFT is explicitly categorized by LCD L34823 as not reasonable and necessary, payment for it cannot be made under the durable medical equipment benefit under Title XVIII § 1861(n) of the Social Security Act. The Appellant's representative asserts that the applicable LCD has not been updated and fails to reflect consideration of developments that have occurred in the past five years and therefore that the ALJ should decline to apply the LCD in this case (Exh. 3, p. 2). In support of such contention, the Appellant provided a Departmental Appeals Board ("DAB") Order in response to the Appellant's LCD complaint, finding that the LCD's record was insufficient to support the validity of the LCD and ordering the parties to indicate whether the record should be closed or whether the parties wanted to engage in discovery or otherwise provide other evidence. (Exh. 4, pp. 27-31). The DAB Order notes that the contractor has proposed to remove the categorical prohibition on coverage of TFTT to permit coverage if specific criteria are met." (Exh. 4, p. 30). The Appellant further notes that on March 6, 2019, the Carrier Advisory Committee recommended Medicare coverage of TTFT, finding that peer-reviewed literature showed the treatment to be safe and effective. (Exh. 3, p. 2). The Appellant also provided the proposed LCD for Tumor Treatment Field Therapy (DL34823). (See Attached CD at Exh. 4). The Appellant's arguments regarding the current LCD's insufficiency, the related DAB developments challenging that LCD, the recent recommendations of the Carrier Advisory Committee, and the proposed LCD, while perhaps indicative of future coverage potential, do not change the fact that a new LCD or contractor-issued policy guidance regarding the coverage of TTFT has not yet been formally published or effectuated. The record in this case before OMHA contains the contactors' *proposed* LCD referenced by the Appellant. The LCD-related DAB proceedings are still ongoing. However, the current LCD L34823 previously cited in this decision remains in effect and indicates non-coverage of TTFT; a proposed LCD does not overrule the LCD's non-coverage provisions. For all the foregoing reasons, the applicable guidance in this case is the LCD L34823.

There is little doubt as to to the seriousness of the Beneficiary's diagnosis and the hoped for benefit and efficacy of the Optune device and TTFT in treating the Beneficiary's condition. The content and reasonableness of the LCD has been appropriately challenged through a separate reconsideration request to CMS and related DAB proceedings. Concerns that an LCD is not supported by the medical community or medical research are not a basis for an ALJ to decline application of a relevant LCD. Although not bound by LCDs, Medicare regulations require ALJs to "give substantial deference to these policies if they are applicable to a particular case." 42 C.F.R. §405.1062(a). The ALJ must explain the reasons why the policy was not followed, and any deviation from the LCD does not have precedential

effect. 42 C.F.R. §405.1062(b). However, the ALJ "may not set aside or review the validity of [an LCD] for purposes of a claim appeal." 42 C.F.R. §405.1062(c). Specifically with respect to tumor treatment field therapy, an ALJ cannot question the validity of a contractor's LCD or substitute one's own judgment on review of the medical research for the medical judgment of the contractor which determined categorically that the device is not reasonable and necessary. Cases involving coverage determinations are not the proper forum for inquiries into the medical reasonableness of otherwise fully considered coverage determinations. LCD L34823, the LCD in effect, states that TTFT (E0766) treatment is non-covered because it is not reasonable and necessary. Because TTFT is categorized by the LCD as not reasonable and necessary, payment for it cannot be made under the durable medical equipment benefit under Title XVIII § 1861(n) of the Social Security Act.

Therefore, the Tumor Treatment Fields Therapy (or electrical stimulation device used for cancer treatment - E0766) provided to the Beneficiary on the Dates of Service, is not reasonable and necessary pursuant to Title XVIII § 1862(a)(1)(A) of the Act and therefore not covered by Medicare Part B.

Limitation of Liability

Under Title XVIII § 1879, Beneficiary and/or Provider/Supplier liability for non-covered Medicare items may be limited under particular circumstances. In pertinent part, limitation of liability may apply to items or services that are excluded under Title XVIII § 1862(a)(1)(A) of the Act. For reasons explained above, the items in this case are ultimately non-covered pursuant to Title XVIII § 1862(a)(1)(A) of the Act; therefore, Title XVIII § 1879 of the Act may apply.

Pursuant to Title XVIII § 1879(a)(2) of the Act, Medicare will limit the Beneficiary's liability for non-covered services if he or she did not know, and could not reasonably have been expected to know, that said services were non-covered. Title XVIII § 1879(a)(2) of the Act also limits the Provider or Supplier's liability for non-covered services if it did not know, and could not reasonably have been expected to know, that said services were non-covered. When both the Beneficiary and the Provider's liability may be limited under Title XVIII § 1879 of the Act, Medicare Part B payment will be made as though Title XVIII §§1862(a)(1)(A), 1862(a)(9) or 1879(g) of the Act did not apply.

A beneficiary who receives services that are not reasonable and necessary under Title XVIII § 1862(a)(1)(A) is considered to have known that the services were not covered if written notice of non-coverage was furnished. In this case, the record contains an indication that the Beneficiary received written notice of non-coverage for Tumor Treatment Fields Therapy (electrical stimulation device used for cancer treatment, E0766). The casefile contained a July 11, 2016 letter written by the Beneficiary appealing Medicare's denial of his physician's authorization request for coverage of TTF therapy using the Optune system. It appears that as of July 11, 2016 that the Beneficiary was reasonably expected to know that the item at issue was non-covered. (Exh. 1, pp. 13-14).

In this case, the Beneficiary knew that Medicare Part B would not cover the Tumor Treatment Fields Therapy (electrical stimulation device used for cancer treatment, E0766). Accordingly, pursuant to Title XVIII § 1879 of the Act the Beneficiary is liable for the non-covered items.

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CONCLUSIONS OF LAW

The electrical stimulation device (Optune) used for cancer treatment (TTFT) (HCPCS E0766) provided to the Beneficiary on the Dates of Service, is not reasonable and necessary pursuant to Title XVIII § 1862(a)(1)(A) of the Act and therefore not covered by Medicare Part B. The Beneficiary is liable for the non-covered items.

ORDER

The Medicare Contractor is hereby **DIRECTED** to process the claim in accordance with this decision.

SO ORDERED

Dated: JUN 28 2019

Leslie Holt
U.S. Administrative Law Judge

Enclosures: Form OMHA-156, Exhibit List